K122580

ENCISION
AEM® LAPAROSCOPIC INSTRUMENTS

510(k) Summary

NOV 9 2012

Device	**Single-Use Hand-Control AEM® Suction Irrigation Electrodes**	
Owner	Encision, Inc. 6797 Winchester Circle Boulder, CO 80301 Phone: (303) 444-2600 Fax: (303) 444-2693	
Contact	James W. Lewis Vice President, Regulatory Affairs and Quality Assurance	
Date of Summary	7 November 2012	
Device Classification	*Trade name*	AEM Disposable Suction Irrigation Electrodes
	Common name	Active Electrosurgical Electrode with AEM
	Classification name	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation & Accessories (Class 2, Product Code GEI, General and Plastic Surgery Panel)
First Predicate	*Trade Name*	ConMed Universal Plus Electrosurgical Suction/Irrigation Electrodes
	Manufacturer	ConMed
	Market Clearance	510(k): K973890
Second Predicate	*Trade Name*	Encision AEM Disposable Electrodes and Handpieces
	Manufacturer	Encision Inc.
	Market Clearance	510(k): K091074

Device Description

Single-Use Hand-Control AEM Suction Irrigation Electrodes (DSIE) are electrosurgical accessories that

- Conduct high-frequency monopolar electrosurgical energy from compatible electrosurgical generators (ESU)
- Provide suction or irrigation

to a surgical site during laparoscopic and endoscopic procedures.

They combine the classic active electrode functions of cutting and coagulation by monopolar energy with the convenience of being able to provide suction and irrigation without having to swap instruments in and out of trocar, port, or cannula.

They are used during open, endoscopic, and laparoscopic surgical procedures to ablate, remove, resect, and coagulate soft tissue where associated hemostasis is required.

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data from aging tests demonstrate greater longevity on the shelf.

Conclusion

DSIE is substantially equivalent to its predicate devices in design and intended use. There are no significant differences between DSIE and the ConMed predicate in electrosurgery or suction/irrigation performance which would raise new issues of safety and effectiveness, performance, function or intended use of the device. There are no significant differences between DSIE and the Encision predicate in electrosurgery or AEM Monitoring performance which would raise new issues of safety and effectiveness, performance, function or intended use of the device. Technological similarities between the predicate devices and the proposed device also demonstrate equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Encision, Inc.
% Mr. James W. Lewis
VP, Regulatory Affairs and
Quality Assurance
6797 Winchester Circle
Boulder, Colorado 80301

Letter Dated: November 9, 2012

Re: K122580
Trade/Device Name: AEM Disposable Suction Irrigation Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 18, 2012
Received: October 19, 2012

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
INDICATIONS FOR USE

510(k) Number (if known): K122580

Device Name: Single-Use Hand-Control AEM Electrosurgical Suction Irrigation Electrodes

Indications for Use:

Sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site. These accessories have applications in general endoscopy and laparoscopy procedures.

AEM instruments incorporate the use of AEM technology and are intended for use with the AEM monitoring system and electrosurgical generators compatible with the AEM system.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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